Protocol: Advance Care Planning with Older Patients who Have End-stage Kidney Disease - Feasibility of a Deferred Entry Randomised Controlled Trial Incorporating a Mixed Methods Process Evaluation

Advance care planning with older patients who have end-stage kidney disease: Feasibility of a deferred entry randomised controlled trial incorporating a mixed methods process evaluation

O'Halloran, P.,* Noble, H., Brazil, K., Fogarty, D., Shields, J., Brown, J., Murtagh, F., Morton, R., Cardwell, C. & Clarke, M.

***p.ohalloran@qub.ac.uk**

Palliative Medicine. 30, 6, p. NP66 10 p., MTE3

DOI: 10.1177/0269216316646056

http://www.abstractserver.com/EAPC2016/uploads/0812-1446218035.pdf

---

Background and rationale: The prevalence of moderate to severe chronic kidney disease (defined as stages 3-5 CKD) has been estimated at 6-8.5% amongst adults in the UK[1–3] and at over 30% in those aged 75 and over[2]. It is associated with rising risks of hospitalisation, cardiovascular events, cognitive impairment and death [4]. The rapidly growing minority of older patients with CKD who progress to end-stage kidney disease (ESKD) are at even greater risk[5]. However, a substantial proportion of patients and their families do not discuss end-of-life care - including withdrawal of dialysis, ICU admission, involvement of specialist palliative care, cardiopulmonary resuscitation, and place of death – with health professionals[6,7]. Moreover, the high incidence of impaired cognitive capacity amongst patients with ESKD limits their ability to make informed choices and places additional decision-making burdens on their families[8,9]. In this situation, advance care planning can be a useful approach to engaging with the patient and their family to help them think through their preferences for care at the end-of-life, leading to better communication between professionals and patients and their families, and improved decision-making should the patient become incapacitated.

Advance care planning (ACP) has been defined as *a process of discussion between an individual, their care providers, and often those close to them, about future care*.[10] It may lead to an advance statement of preferences; an advance decision to refuse treatment (ADRT); or to the appointment of someone with lasting power of attorney. ACP can be a complex and challenging process for patients, their families and professionals, raising cultural and personal sensitivities around death[11]; with uptake influenced by a range of social and cultural beliefs, and organisational issues[12]. Nevertheless, emerging evidence suggests ACP can reduce rates of hospital admission, increase use of hospice and palliative care, facilitate the delivery of care that is less aggressive, increase patient and family satisfaction, and reduce anxiety and depression in surviving relatives[11,13–15]. Consequently, in the UK ACP is seen as good practice for those with long-term conditions, or who are at the end of life[16,17]. It is also recognised as a mark of high quality care in CKD and ESKD[18–20].

Research into ACP in CKD is limited. A recent systematic review[21] found some evidence that ACP led to increased well-being and reduced anxiety amongst patients and families. However, most studies were descriptive, and intervention studies measured a limited set of outcomes. Issues for research included poor agreement between surrogate decision-makers and patients on end-of-life preferences such as stopping dialysis; the difficulty health professionals and patients have in knowing how and when to discuss end-of-life care; and that patients on dialysis may greatly overestimate their life expectancy. There is also little available data on cost-effectiveness to guide decision makers in allocating resources for ACP[22]. Given that ACP is recognised as good practice and yet is a challenging process, research is needed to address issues in relation to implementation, patients' readiness to engage, conservative treatment, withdrawal of dialysis, quality of life, costs, and patient and family outcomes[23]. National guidance on implementing ACP recommends that peer education of patients should be included, using expert patients[10]; and this has been used successfully amongst dialysis patients[24]. Older patients with ESKD are suitable for inclusion in an evaluation of ACP amongst older adults because they exhibit the mixture of functional decline and co-morbidity typical of frail older people[5]. Implementation and evaluation of ACPs is challenging,[25] so intervention processes and research methods should be thoroughly tested before larger scale evaluations are attempted. Therefore, following MRC guidance on the evaluation of complex interventions[26], we propose a study to determine the feasibility of a randomised controlled trial (RCT), including a mixed methods process evaluation, to evaluate ACP delivered by professionals (working in partnership with peer supporters), for older patients with ESKD.

Aims and objectives: We begin with summary objectives for the proposed full trial so that the relevance of the objectives for the feasibility study can be appreciated. *Full trial objectives:* (i) To measure the degree to which implementation of ACP results in desired outcomes for patients with CKD and their families; (ii) to estimate the cost-effectiveness of ACP compared to standard care; and (iii) to explain how the process of implementation and the organisational context affect the success or failure of the intervention.

Aim of the feasibility study: To determine the feasibility of conducting a deferred entry RCT, incorporating a mixed methods process evaluation, to evaluate ACP with patients who have ESKD.

Objectives of the feasibility study: The research will enable us to investigate the following:

- Acceptability of the intervention to patients, their carers and to health professionals.
- Optimal systems for delivering ACP, including the recruitment, training and retention of peer educators
- Recruitment, retention and participation rates
- Effect sizes that might help inform sample-size estimates for a full trial
- Randomisation procedures and participants' willingness to enter a deferred entry trial
- The suitability of a twelve-week deferral period and a nine month process evaluation.
- The suitability of survey instruments and outcome measures, including sensitivity of the instruments to detect a change in outcomes
- Time needed to collect and analyse data
- Estimated costs of delivering ACP and methods for assessing cost effectiveness in a full trial.

Criteria for progression to a full trial: A protocol for a full trial will be developed if the findings indicate that the intervention is acceptable to patients, their carers and to health professionals; peer educators can be recruited, trained, and retained; ACP can be readily implemented by relevant staff; recruitment, participation, and retention rates are likely to be adequate for a full trial; the instruments are not excessively burdensome to patients or data collectors, and show acceptable reliability and validity; an economic evaluation is feasible.

Design and methodology: Patients and their nominated carers will be recruited to a deferred entry RCT. A traditional RCT could be unethical as ACP issues would be raised but not followed through with patients in the control group. Consequently, we plan a deferred entry trial, where participants are randomised either to an intervention group or a deferred entry control group, as recommended in guidance published by the Medical Research Council and the National Institute of Health Research (NIHR)[27]. Participants in the deferred entry group have outcomes measured contemporaneously with the immediate entry group but receive the intervention only after trial data collection for the immediate entry group is complete[28]. Patients, their nominated carers and staff participants will be recruited into the process evaluation, which will last for 12 months from enrolment in the study. This will be underpinned by realist evaluation methodology[29] and use qualitative and observational methods to evaluate issues influencing the success of implementation[30–32].

Methods: Setting, participants, interventions, and outcomes

Study setting: Two sites: the Regional Nephrology Unit at Belfast City Hospital, Belfast Health and Social Care Trust (BHSCT) and the Renal Unit at Antrim Area Hospital, Northern HSCT.

Eligibility criteria - patients: Attending the renal units above; aged 65 years or more; with ESKD and receiving RRT; with capacity to understand, retain, and weigh the necessary information and communicate their decisions[10]; identified by their consultant as having worsening symptoms, functional decline, and two or more co-morbidities, and as not expected to die in the next three months.

Eligibility criteria - carers: aged 18 years or older; able to read, write, and speak English; identified by the patient as the patient's nominated carer and willing to represent the patient's wishes should they lose decision-making capacity.

Intervention: This will take place in an outpatient context. Participants will be offered the opportunity to complete an ACP by a nurse trained as an ACP facilitator, who will discuss the process with them using the booklet, "Your life and your choices: plan ahead," produced by the Northern Ireland Public Health Agency and Macmillan Cancer Support[33]. One-to-two weeks later, they will complete an ACP document with the help of the ACP facilitator, working together with trained expert patients who will provide peer support at the time of ACP completion and subsequently by telephone [10,24,34,35], assisted where necessary by the ACP facilitator. The ACP document will be based on that used within the BHSCT ("A record of my wishes", recently developed by the Northern Ireland Palliative and End of Life Care Implementation Group and based on the booklet, "Your life and your choices: plan ahead") which results in the identification of a nominated person to help in decision-making as well as the following: a) What the patient would like to happen in the future; b) What the patient would not want to happen; c) Recording the presence and broad content of an ADRT if it already exists; d) Preferred place of care at the end-of-life; e) Special requests.

The patient will be encouraged to keep the ACP with them and to make it available to anyone caring for them. A summary of the patient's wishes in the ACP will be kept with their medical notes and copied to their GP, relevant social and community services, and to out-of-hours and ambulance services. The ACP will be reviewed if circumstances change or the patient changes their mind, and in any case after twelve weeks. Participants in the deferred entry group will be offered the intervention twelve weeks after the immediate entry group. Our approach to implementation of the ACP will be informed by a realist review of the literature[36] and draw on the Consolidated Framework For Implementation Research,[37] which focuses on intervention characteristics, organisational setting, and the characteristics of the individuals involved.

Baseline and outcome data: Baseline data will include socio-economic status, education, CKD stage, co-morbidities and time since beginning RRT[38,39]

RCT outcome measures: Quality of life as measured by the Kidney Disease Quality of Life instrument – Short Form (KDQOL-36™)[40]. Degree of cognitive impairment as measured by the Isaacs Set Test (IST 15)[41]. Degree of anxiety, depression, well-being, functioning and risk as measured by the Clinical Outcomes in Routine Evaluation measure (CORE 34)[42]. The degree to which the patient felt that they had shared in decision-making about their care as measured by the Patient Experience of Shared Decision Making (SHARED) instrument[43]. Agreement between the patient and their nominated carer in terms of the patient's preferences. We will measure this by asking the carer to make an independent assessment of the patient's preferences in relation to the key information covered by the ACP intervention (a-e above), before taking part in the ACP.

Participant timeline

Immediate entry group: Time 1. Following enrolment and prior to receiving the intervention, patients randomised to the immediate intervention group will complete the IST 15, CORE 34, and KDQOL-36™, and SHARED. Their nominated carer will make an independent assessment of the patient's ACP preferences before the patient receives the information booklet. Subsequently, the patient and (if the patient wishes) the carer will participate in the ACP intervention.

Time 2. At two weeks following the intervention, the patient will complete the CORE 34 and SHARED, and review their ACP. The nominated carer will make a second independent assessment of the patient's preferences.

Time 3. At 12 weeks the patient will again complete CORE 34, KDQOL-36™, and SHARED and both patient and carer will review the ACP and make any desired changes.

Deferred entry group: Patients (and their nominated carers) randomised to the deferred entry group will have outcomes measured contemporaneously with the immediate entry group but receive the intervention only after trial data collection for the immediate entry group is complete. At 24 weeks the patient will again complete CORE 34, KDQOL-36™, and SHARED and both patient and carer will review the ACP and make any desired changes.

Process evaluation: Participants will be followed for 12 months (or until bereavement if earlier) from enrolment in the study.

Sample size for the RCT: We will recruit 40 patient-carer dyads. Assuming 25% attrition[44], this sample size is thought to provide sufficient numbers to allow feasibility to be estimated and to offset the bias in estimates of effect size produced by very small samples[45,46].

Allocation: Participants will be randomly assigned to either immediate entry or deferred entry groups in a 1:1 ratio with allocation as per a computer generated randomisation using permuted blocks of random sizes. To ensure concealment block sizes will not be disclosed.

Analysis of trial data: Outcomes measured at 2/52 and 12/52 (see Table 1.) for the immediate entry group (who at these stages have received the intervention) will be compared with those of the deferred entry group at 2/52 and 12/52 (who at that stage have not received the intervention) using independent-sample t-tests or Mann-Whitney U tests, as appropriate. The paired t-test or Wilcoxon signed rank test will be used to compare changes in outcome measures within the immediate entry and deferred entry groups.

Economic evaluation: We will document healthcare resource use associated with the delivery of the ACP using case report forms and patient/carer diaries for recording all healthcare appointments or hospital admissions, together with chart review of enrolled patients and investigation of routinely collected data such as Hospital Episode Statistics to ascertain inpatient and outpatient use. These will be valued according to appropriate tariffs, allowing comparison of mean costs per patient during the 12 week period of the trial. We will estimate health utility (i.e. QALY weights) at 12 weeks from the SF-12 contained within the KDQOL-36 questionnaire. Mean costs (including volume of resource use) and mean health outcomes per allocated group will be reported with 95% confidence intervals. Mean costs will be presented as unadjusted and adjusted for any baseline differences in age, sex or socio-economic status.

Process evaluation: We will conduct five focus groups with the following staff to elicit their experience with ACP and their views on barriers and enablers of implementation: four intervention facilitators, four peer supporters, four members of medical staff, four members of nursing/AHP staff, and those training staff in ACP. In addition, we will interview four patients and four nominated carers in relation to their experiences of ACP twelve weeks after they have used the intervention. We will also observe staff training for ACP; carry out documentary analysis; and develop a process map[47] of the personnel and systems involved in managing ACP.

Outcome measures from the process evaluation: We will measure the proportion of patients who die during the nine months of the study whose end of life wishes are complied with, as measured by a comparison of their ACP and the record of the circumstances of their death in the medical notes and in a survey of bereaved nominated carers. We will compare carers whose relative experienced care broadly in alignment with their wishes with carers of those who did not, in terms of their satisfaction with care, as measured by the After-Death Bereaved Family Interview[48] and level of depression measured by the Patient Health Questionnaire (PHQ9)[49].

Analysis of observational data: Interviews will be digitally recorded and transcribed verbatim. Each piece of interview and other data will be coded according to the initial theory derived from CFIR and the realist review to allow indexing and retrieval in a suitable database. The documentary evidence, process map, and interview transcripts will be reviewed searching for configurations that support, contradict and link theory, seeking to explain outcomes.

Outcomes and outputs: The immediate outcome of this study will be an appraisal of the feasibility of a full study, with an analysis of the factors crucial to successful implementation

of ACP, paving the way for a future definitive evaluation of the impact of ACP on the well-being of patients with complex co-morbidities and their families, and identification of the key factors leading to successful implementation. The full study will evaluate the impact of ACP on patients who have ESKD and on associated costs, with anticipated benefits of greater adherence to their wishes at the end of life; reduced rates of hospital admission; greater use of hospice and palliative care services; less anxiety and depression; increased perception of shared decision-making; and greater well-being, and physical and social functioning. Carers should experience greater agreement with patients' wishes, greater satisfaction with care, and less depression on bereavement.

Timetable and milestones

Activity / Months	**Pre-start**	**0-6**	**6-12**	**12-18**	**18-24**
Ethical and governance approval					
Project set-up/realist review of the literature					
RCT					
Process and economic evaluations					
Interviews with patients and carers					
Interviews with professionals					
Analysis of data					
Final report and development of full trial proposal					

References

1. Stevens PE, O'Donoghue DJ, de Lusignan S, Van Vlymen J, Klebe B, Middleton R, Hague N, New J, Farmer CKT. Chronic kidney disease management in the United Kingdom: NEOERICA project results. *Kidney Int*. 2007;72(1):92-99. doi:10.1038/sj.ki.5002273.

2. Roth M, Roderick P, Mindell J. *National Statistics Health Survey for England - 2010, Respiratory Health*. Leeds: The Health and Social Care Information Centre; 2011:1-27. http://www.hscic.gov.uk/pubs/hse10report.

3. Jameson K, Jick S, Hagberg KW, Ambegaonkar B, Giles A, O'Donoghue D. Prevalence and management of chronic kidney disease in primary care patients in the UK. *Int J Clin Pract*. 2014;68:1110-1121. doi:10.1111/ijcp.12454.

4. National Collaborating Centre for Chronic Conditions. *Chronic Kidney Disease*. London: Royal College of Physicians; 2008:1-204.

5. Anderson S, Halter JB, Hazzard WR, Himmelfarb J, Horne FM, Kaysen G a, Kusek JW, Nayfield SG, Schmader K, Tian Y, Ashworth JR, Clayton CP, Parker RP, Tarver ED, Woolard NF, High KP. Prediction, progression, and outcomes of chronic kidney disease in older adults. *J Am Soc Nephrol*. 2009;20(6):1199-1209. doi:10.1681/ASN.2008080860.

6. Arulkumaran N, Szawarski P, Philips BJ. End-of-life care in patients with end-stage renal disease. *Nephrol Dial Transplant*. 2012;27(3):879-881. doi:10.1093/ndt/gfs028.

7. Davison SN. Advance care planning in patients with chronic kidney disease. *Semin Dial*. 2012;25(6):657-663. doi:10.1111/sdi.12039.

8. Murray AM, Tupper DE, Knopman DS, Gilbertson DT, Pederson SL, Li S, Smith GE, Hochhalter AK, Collins AJ, Kane RL. Cognitive impairment in hemodialysis patients is common. *Neurology*. 2006;67(2):216-223. doi:10.1212/01.wnl.0000225182.15532.40.

9. Holley JL. Advance care planning in CKD/ESRD: an evolving process. *Clin J Am Soc Nephrol*. 2012;7(6):1033-1038. doi:10.2215/CJN.00580112.

10. Royal College of Physicians. *Advance Care Planning. Concise Guidance to Good Practice Series*. London: Royal College of Physicians; 2009. http://www.rcplondon.ac.uk/resources/concise-guidelines-advance-care-planning.

11. Mullick A, Martin J, Sallnow L. An introduction to advance care planning in practice. *BMJ*. 2013;347(October):1-6. doi:10.1136/bmj.f6064.

12. Lovell A, Yates P. Advance Care Planning in palliative care: A systematic literature review of the contextual factors influencing its uptake 2008-2012. *Palliat Med*. 2014;28(8):1026-1035. doi:10.1177/0269216314531313.

13. Houben CHM, Spruit M a, Groenen MTJ, Wouters EFM, Janssen DJ a. Efficacy of advance care planning: a systematic review and meta-analysis. *J Am Med Dir Assoc*. 2014;15(7):477-489. doi:10.1016/j.jamda.2014.01.008.

14. Detering K, Hancock A, Reade M, Silvester W. The impact of advance care planning on end of life care in elderly patients: randomised controlled trial. *Bmj*. 2010;340(7751). doi:10.1136/bmj.c1345.

15. Brinkman-Stoppelenburg A, Rietjens JA, van der Heide A. The effects of advance care planning on end-of-life care: A systematic review. *Palliat Med*. 2014;28(8):1000-1025. doi:10.1177/0269216314526272.

16. Leadership Alliance for the Care of Dying People. *One Chance to Get It Right.* London: Department of Health; 2014:1-168. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/323188/One_chance_to_get_it_right.pdf.

17. NHS Improving Quality. *Planning for Your Future Care: A Guide*. Leeds: NHS Improving Quality; 2014:1-16. http://www.nhsiq.nhs.uk/resource-search/publications/eolc-planning-for-future-care.aspx.

18. Department of Health. *National Service Framework for Renal Services Part Two : Chronic Kidney Disease , Acute Renal Failure and End of Life Care*. London: Department of Health; 2005.

19. National Institute for Health and Clinical Excellence. Chronic kidney disease quality standard. 2012. http://publications.nice.org.uk/chronic-kidney-disease-quality-standard-qs5. Accessed July 1, 2014.

20. Crail S, Walker R, Brown M. Renal supportive and palliative care: position statement. *Nephrology*. 2013;18:393-400. http://onlinelibrary.wiley.com/doi/10.1111/nep.12064/full. Accessed August 27, 2014.

21. Luckett T, Sellars M, Tieman J, Pollock CA, Silvester W, Butow PN, Detering KM, Brennan F, Clayton JM. Advance care planning for adults with CKD: a systematic integrative review. *Am J Kidney Dis*. 2014;63(5):761-770. doi:10.1053/j.ajkd.2013.12.007.

22. CRD. *Advance Care Planning*. York: Centre for Reviews and Dissemination; 2013. https://www.york.ac.uk/inst/crd/pdf/Advance care planning.pdf. Accessed January 27, 2015.

23. Holley JL, Davison SN. Advance care planning in CKD: clinical and research opportunities. *Am J Kidney Dis*. 2014;63(5):739-740. doi:10.1053/j.ajkd.2014.02.005.

24. Perry E, Swartz J, Brown S, Smith D, Kelly G, Swartz R. Peer Mentoring: A Culturally Sensitive Approach to End-of-Life Planning for Long-Term Dialysis Patients. *Am J Kidney Dis*. 2005;46(1):111-119. doi:10.1053/j.ajkd.2005.03.018.

25. Lund S, Richardson A, May C. Barriers to advance care planning at the end of life: an explanatory systematic review of implementation studies. *PLoS One*. 2015;10(2):e0116629. doi:10.1371/journal.pone.0116629.

26. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. *Developing and Evaluating Complex Interventions: New Guidance*. London: Medical Reseach Council; 2008. http://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/. Accessed March 2, 2015.

27. Evans CJ, Stone KA, Manthorpe J, Higginson IJ. *MRC Guidance on Developing and Evaluating Complex Interventions: Application to Research on Palliative and End of Life Care. Methods Review 15*. London: NIHR School for Social Care Research London School of Economics and Political Science Houghton Street London WC2A 2AE; 2013:1-37. www.sscr.nihr.ac.uk.

28. Higginson IJ, Booth S. The randomized fast-track trial in palliative care: role, utility and ethics in the evaluation of interventions in palliative care? *Palliat Med*. 2011;25(8):741-747. doi:10.1177/0269216311421835.

29. Pawson R, Tilley N. *Realistic Evaluation*. SAGE Publications Ltd; 1997.

30. Higginson IJ, Evans CJ, Grande G, Preston N, Morgan M, McCrone P, Lewis P, Fayers P, Harding R, Hotopf M, Murray S a, Benalia H, Gysels M, Farquhar M, Todd C. Evaluating complex interventions in end of life care: the MORECare statement on good practice generated by a synthesis of transparent expert consultations and systematic reviews. *BMC Med*. 2013;11:111. doi:10.1186/1741-7015-11-111.

31. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. *BMJ*. 2006;332(7538):413-416. doi:10.1136/bmj.332.7538.413.

32. Moore G, Audrey S, Barker M, Bonell C, Hardeman W, Moore L, Cathain AO, Tinati T, Wight D, Baird J. Process evaluation of complex interventions: UK Medical Research Council (MRC) guidance. 2014.

33. *Your Life and Your Choices: Plan Ahead*. London: Macmillan Cancer Support and Northern Ireland Public Health Agency; 2013. http://be.macmillan.org.uk/be/p-21065-your-life-and-your-choices-plan-ahead-northern-ireland.aspx. Accessed March 12, 2015.

34. National Kidney Foundation. *Benefits of Peer Support in People with Chronic Kidney Disease*. New York: National Kidney Foundation; 2009. www.kidney.org.

35. Beard, C., Mukuro, F., McQuade, M., Willis, C; Wood E. *You're Not Alone : Peer Support for People with Long Term Conditions*. NHS Kidney Care; 2013:1-22. http://www.lsckpa.org.uk/cdata/45832/docs/5724056_1.pdf.

36. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: realist syntheses. *BMC Med*. 2013;11(1):21. doi:10.1186/1741-7015-11-21.

37. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander J a, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. 2009;4:50. doi:10.1186/1748-5908-4-50.

38. O'Neill J, Tabish H, Welch V, Petticrew M, Pottie K, Clarke M, Evans T, Pardo Pardo J, Waters E, White H, Tugwell P. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. *J Clin Epidemiol*. 2014;67(1):56-64. doi:10.1016/j.jclinepi.2013.08.005.

39. Lewis JM, DiGiacomo M, Currow DC, Davidson PM. Dying in the margins: understanding palliative care and socioeconomic deprivation in the developed world. *J Pain Symptom Manage*. 2011;42(1):105-118. doi:10.1016/j.jpainsymman.2010.10.265.

40. Gibbons E, Fitzpatrick R. *A Structured Review of Patient-Reported Outcome Measures for People with Chronic Kidney Disease*. Oxford: Patient-reported Outcome Measurement Group, Department of Public Health, University of Oxford; 2010. http://phi.uhce.ox.ac.uk/pdf/PROMS_Oxford_KidneyReview_24112010.pdf.

41. Isaacs B, Kennie a. T. The Set Test as an Aid to the Detection of Dementia in Old People. *Br J Psychiatry*. 1973;123(4):467-470. doi:10.1192/bjp.123.4.467.

42. Evans C, Mellor-Clark J, Margison F, Barkham M, Audin K, Connell J, McGrath G. CORE: Clinical Outcomes in Routine Evaluation. *J Ment Heal*. 2000;9(3):247-255. doi:10.1080/713680250.

43. GEM. Patient Experience of Shared Decision Making (SHARED). *Grid-Enabled Meas Database*. 2014;(November). https://www.gem-measures.org/public/MeasureDetail.aspx?cat=2&mid=1517&tab=0. Accessed October 17, 2014.

44. Kirchhoff KT, Hammes BJ, Kehl K a, Briggs L a, Brown RL. Effect of a disease-specific planning intervention on surrogate understanding of patient goals for future medical treatment. *J Am Geriatr Soc*. 2010;58(7):1233-1240. doi:10.1111/j.1532-5415.2010.02760.x.

45. Julious S a. Sample size of 12 per group rule of thumb for a pilot study. *Pharm Stat*. 2005;4(4):287-291. doi:10.1002/pst.185.

46. Hertzog MA. Considerations in Determining Sample Size for Pilot Studies. *Res Nurs Health*. 2008;31(January):180-191. doi:10.1002/nur.20247.

47. Trebble TM, Hansi N, Hydes T, Smith MA, Baker M. Process mapping the patient journey: an introduction. *BMJ*. 2010;341(c4078). doi:10.1136/bmj.c4078.

48. Teno JM, Clarridge B, Casey V, Edgman-Levitan S, Fowler J. Validation of Toolkit After-Death Bereaved Family Member Interview. *J Pain Symptom Manage*. 2001;22(3):752-758. http://www.ncbi.nlm.nih.gov/pubmed/11532588.

49. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med*. 2001;16(9):606-613.